

**REMARKS**

Claims 1-20 are pending in this application. Claims 7 and 12 - 20 are withdrawn from consideration at this time, however, subject to a restriction requirement. Claims 2, 5-6 and 11 are cancelled. Accordingly, claims 1, 3-4 and 8-10 are those being examined on the merits, and all stand rejected by the Examiner, per the Office Action of February 9, 2004.

**Claim Objections**

Claim 10 is objected to for being in improper form. Claims 8 and 9 have the same improper form as that of claim 10- (although not specifically objected to by the Examiner). Therefore, claims 8-10 are amended to eliminate the improper multiple dependency, now referring to preceding claims in the alternative only. Applicants submit that no new matter is added with these amendments.

**Rejection under 35 USC § 101 - Utility**

The Examiner has rejected claims 1-6 and 8-11, asserting that these claims lack either a specific and substantial utility or a well-established utility, as required by 35 USC § 101. Applicants have asserted utility of the MEG-3 protein relating to the expression of MEG-3 in mesangial cells but the Examiner rejects these utilities by stating that other genes could be used for the same purposes. Applicants respectfully submit that this is irrelevant to the asserted utilities of the claimed invention. It is the claimed invention that must be novel, not its utility. The requirement for the claimed subject matter to have a

specific and substantial utility does not require that the claimed invention have a utility that can be met by no other product, process, or technology.

Further, Applicants' opinion as to utility is typically sufficient to support utility, and the Examiner's opinion to the contrary is not sufficient basis for finding lack of utility. As stated in MPEP § 2107.01, I., "Where an applicant has set forth a specific and substantial utility, courts have been reluctant to uphold a rejection under 35 U.S.C. § 101 solely on the basis that the applicant's opinion as to the nature of the specific and substantial utility was inaccurate."

Regarding specific utility, Applicants respectfully submit that the Examiner has misinterpreted the cautions of § MPEP 2107.01 regarding lack of utility for inventions claiming a polynucleotide whose use is simply "gene marker" or "chromosome marker" in finding that the presently claimed invention lacks a specific utility. Claiming a generic "gene marker" or "chromosome marker" (not sufficient for utility) is not at all the same as claiming a specific gene marker for mesangial cells (sufficient for utility). In the former case, the type identified in MPEP § 2107.01 as lacking a specific utility, the gene to be marked is not identified, or known. Such a use represents merely a blanket claim that the polynucleotide could be used as a marker for "some" gene. In the instant case, it is definitively known that the MEG-3 protein is expressed in mesangial cells, and thus the claimed utility for a mesangial cell marker is sufficient to meet the requirement for the claimed subject matter have a specific utility. Further, as detailed in MPEP § 2107.01, when "an applicant discloses a specific biological activity [in the instant case, expression of MEG-3 in mesangial cells] and reasonably correlates that activity to a disease condition" [proliferation of mesangial cells and accumulation of extracellular mesangial

matrix in the pathology of glomerulosclerosis including diseases such as chronic nephritis and diabetic nephrology - p. 1, lines 17-21 of the instant application] then such assertions “are sufficient to define a specific utility for the invention.” See MPEP § 2107.01, I., *Specific Utility*.

Regarding substantial utility, “an assay method for identifying compounds that themselves have a “substantial utility” defines a “real world” context of use” and thus meet the requirement for substantial utility. See MPEP § 2107.01, I., *Substantial Utility*. And as further explained, “*any* reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit *should be accepted as sufficient*, at least with regard to defining a “substantial” utility.” *Id.* Emphasis added.

Reconsideration and withdrawal of the utility rejection under 35 U.S.C. §101 is therefore requested.

#### Rejection under 35 USC § 112, para. 1 - Enablement

The Examiner has rejected claims 1-6 and 8-11 under 35 USC §112, para.1, for reasons of enablement. The rejection is linked to the above-discussed utility rejection under §101, the Examiner asserting that “since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility... one skilled in the art clearly would not know how to use the claimed invention.” See Office Action, p. 8.

Applicants respectfully disagree, and submit that 1) there is both a specific asserted utility and a well established utility, and 2) that it is conclusory to state that “one skilled in the art would *clearly* not know how to use the claimed invention” given that no

evidence to such lack of knowledge by anyone skilled in the art is presented by the Examiner to support this statement. Further, given that the instantly claimed invention asserts specific, substantial and well-established utility in identifying mesangial cells, detecting abnormalities in mesangial cells, studying the functions of mesangial cells and investigating causes of diseases relating to mesangial cells (i.e. glomerulonephritis) for which the claimed subject matter in this application can be used, Applicants respectfully submit that one skilled in the art would know how to use the claimed invention.

Further, the Examiner states that “even if the specification were enabling of how to use the MEG-3 polypeptide (or nucleic acid), [such] enablement would not be found commensurate in scope with the [pending] claims.” See Office Action, p. 8. Applicants respond by calling the Examiner’s attention to the currently amended claims, which limit the scope of the claimed subject matter to that commensurate with the scope of enablement of the specification. Reconsideration and withdrawal of the enablement rejection under 35 U.S.C. § 112, para. 1 is therefore requested.

Rejection under 35 USC § 112, para. 1 - Written Description

Applicants have amended claim 1 and cancelled claims 2, 5, and 6 such that pending claims now claim a protein comprising only the single species SEQ ID NO: 2. Moreover, by canceling claim 5, the Examiner’s rejection regarding lack of written description for a DNA **complement** rather than the DNA coding for the protein of SEQ ID NO:1 is no longer an issue. Applicants submit that in light of these claim amendments and cancellations, the specification meets the written description requirements of § 112, para. 1 and so the written description rejection is now moot. Reconsideration and

withdrawal of the written description rejection under 35 U.S.C. §112, para. 1, is therefore requested.

Rejection under 35 USC § 112, para. 2 - Indefiniteness

Claim 1 is herein amended to delete the phrase “”or a protein comprising the amino acid sequence of SEQ ID NO:2 in which one or more amino acids are replaced, deleted, added, and/or inserted, and being functionally equivalent to the protein comprising the amino acid sequence of SEQ ID NO:2.” Claim 5 is cancelled. Therefore, Applicants respectfully submit that all pending claims, as currently amended, are definite. Reconsideration and withdrawal of the indefiniteness rejection under 35 U.S.C. §112, para. 2, is therefore requested.

Priority Claim

As presented in the above arguments, Applicants believe that the instant application meets the utility requirements of 35 U.S.C. §112, para. 1. Therefore, Applicants submit that the presently claimed invention is entitled to benefits of the priority claim to Japanese Patent Application NO. JP 11/123561 filed April 30, 1999 in accordance with 37 CFR §1.55 and 35 U.S.C. §119. Reconsideration and granting of priority back to April 30, 1999 is therefore requested.

Rejection under 35 USC § 102(a) and § 102(e) - Anticipation

Claims 1, 3, 5, 6, 8, 9, and 11 stand rejected as being anticipated by Ottenwaelder et al. (Database PIR\_76, Accession No. T46394, February 4, 2000; Database GenEmbl

nucleotide sequence Accession No. AL137555) and claims 1, 3, 5, 6, and 8-11 stand rejected as being anticipated by Lal et al. (US20020091244, priority date December 31, 1997 from U.S. Application Serial No. 09/002,485).

Ottenwaelder et al. discloses a cDNA clone encoding a hypothetical protein encoded by mRNA from adult testis clone DKFZp-434H0820 that is 94.6% identical to the protein of SEQ ID No:2 of the instant invention. Lal et al. disclose a protein (SEQ ID NO:39) that is identical to amino acids 556-578 of SEQ ID NO:2 of the instant application, encoded by a nucleic acid molecule that is 99.8% identical to nucleotides 1682-2227 of SEQ ID NO:1 of the instant application. Neither references teaches SEQ ID NO:2 in its entirety.

In view of the amendments to claim 1, and the cancellation of claims 5 and 11, Applicants submit that the pending claims, as currently amended to require "A protein comprising *the amino acid sequence of* SEQ ID NO:2", are novel over both references. Emphasis added. Applicants also submit that the priority claim is valid for the instant application, and thus the Ottewaelder et al. reference is not prior art under 35 USC §102(a). Reconsideration and withdrawal of the anticipation rejections under 35 U.S.C. §102(a) and (e), is therefore requested.

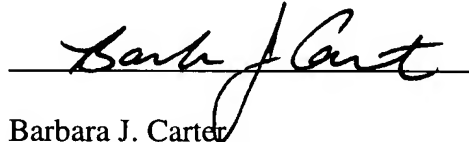
### CONCLUSION

It is respectfully submitted that all pending claims are in condition for allowance. Reconsideration of the claims and a notice of allowance is therefore requested. If the Examiner has any questions in regard to this matter, Applicants respectfully request that the Examiner contact the Applicants' attorney at the telephone number listed below.

Applicants herein petition for a one-month extension, and enclose a check for \$110 to cover the one-month extension fee. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

Date: June 9, 2004

Respectfully submitted,

A handwritten signature in cursive script, reading "Barbara J. Carter", is written over a horizontal line.

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